Claim 1 has been amended to incorporate the limitations of original dependent claim 7. Support for the amendment, therefore, is found in original claim 7.

With a view to the rejection under 35 USC § 112, second paragraph, discussed further below, claim 8 has been amended to place it in better form, and claim 21 has been added to recite the "optional" limitation of original claim 8 which was deleted from claim 8. Support for the amendments to claim 8 and for claim 21, is found in original claim 8 and in the specification at, for example, page 4, lines 1-5.

Support for product-by-process claims 22 and 23 is inherent from the claims from which they depend.

It respectfully is submitted that the amendments presented to claim 1 and 8, and that added claims 21-23, do not introduce new matter, and approval of the amendments respectfully is solicited.

As noted in the preliminary remarks above, the Examiner imposed a four-way restriction requirement which divided the claims into the following Groups:

Group I drawn to "compounds, composition" containing claims 1-8;

Group II drawn to "composition and method of use for lowering cholesterol and triglyceride" containing claims 9-14;

Group III drawn to "composition and process for lowering cholesterol and triglyceride" containing claim 15; and

Group IV drawn to "composition and process for making the compounds" containing claims 16-20.

In accordance with restriction practice, the subject matter of claims 1-6 and 8 (Group I) is hereby elected for prosecution with traverse. However, for the reasons presented

below, it respectfully is submitted that the restriction between Groups I, III and IV should be withdrawn.

Initially, with regard to the reasoning advanced in support of the restriction, it appears that the Examiner inadvertently overlooked that the Group IV process claims and the Group III process claim are related. Clearly, claims 15 and 16 both recite ***a process*** for preparing a phytosterol and/or phytostanol ester compound.

Claim 15 reads:

> 15. **A process for preparing a phytosterol and/or phytostanol ester compound** comprising esterifying a free phytosterol, a free phytostanol, or a mixture thereof with a n-3 polyunstaurated fatty acid having from 18 to 22 carbon atoms and at least three carbon-carbon double bonds.

And claim 16 reads:

> 16. **A process for preparing a phytosterol and/or phytostanol ester compound** comprising:
>
> (a) mixing, in the absence of solvent, a free physterol and/or phytostanol, an ester of a n-3 polyunsaturated fatty acid (PUFA), and an interesterification catalyst to form a reaction mixture; and
>
> (b) heating the reaction mixture to obtain interestserification of the phytosterol and/or phytostanol with the ester of the n-3 PUFA.

The Examiner's assertion that Group III (claim 15) is drawn to "composition and ***process for lowering the cholesterol and triglycerides***" (paper No. 2, at 2), clearly is in error, since claim 15 does not recite anything about "lowering cholesterol or triglycerides."

Claims 15 and 16-20 are all drawn to processes for preparing compounds, and are clearly related. Therefore, Group III (claim 15) and Group IV (claims 16-20) are related, and the restriction requirement between those two Groups must be withdrawn.

With regard to the restriction between Groups I and IV, the Examiner gave ***no reason whatsoever*** to support the restriction. (See paper No. 2, p.3, lines 1-2). That however, was the Examiner's burden. See MPEP § 803 ("Examiners ***must*** provide reasons and/or examples to support conclusions" that restrictions are proper). In fact, to the contrary, the Examiner has only stated that the "[i]nventions of Group I and Group IV are related as process of making and product made" (paper No. 2, at 2), which only supports a conclusion that the Group I and the Group III and IV claims should be examined together.

Because the Examiner has not been met his burden, the restriction between the Group I claims and the Group III and IV claims must be withdrawn.

In any event, we demonstrate that the claims of Groups I, III, and IV should be examined together, and with added product-by-process claims 22 and 23. As the Examiner will note, the manner of presentation of the Group I, III, and IV claims and product-by-process claims 22 and 23 added by this amendment, makes clear that the product, process, product-by-process, and composition subject matter are related. There is, quite clearly, a disclosed relationship, and therefore, it follows that the claims of these groups are not independent. See MPEP § 802.01, *i.e.*, if claims are related, they are not independent. That, therefore, only leaves the question whether the three groups are distinct, and when inventions are related and ***not*** distinct, restriction is never proper. MPEP § 806(C).

In evaluating distinctness, a factor to be considered is that, as set forth in MPEP § 802.01, distinctness requires a finding that the inventions "ARE PATENTABLE (novel and unobvious) OVER EACH OTHER". The Examiner has not made any such showing.

So, too, the Examiner has offered ***no evidence*** that a process as is claimed in Groups III and IV could (or can be) used to make products other than and different from the

products and compositions claimed, or that the products claimed could be made by processes different from those claimed, which is a burden that the Examiner must meet in a properly asserted restriction requirement. See MPEP § 806.05(f). Similarly, with regard to the Group II claims, the Examiner has not provided any evidence that the "process for using the product claimed" could be practiced using "another materially different product." (See paper No. 2, at p. 3). "The burden is on the Examiner to provide an example." See MPEP § 806.05(h). Merely repeating the test for restriction verbatim, is not an example. And the Examiner has not set forth ***any*** rationale that would have any relevance to the foregoing.

Thus, it must be found that, on the present record, claims 1-6, 8, 15-20, 22, and 23 presented above, are not independent or distinct, and when neither of those considerations is present, restriction is not proper. Thus, claims 1-6, 8, 15-20, 22, and 23 must be examined in this application.

Further for completeness, the product, process, product-by-process, and composition claims are all "linked", and as set forth in MPEP § 809, when linking claims are present, "the linking claims ***must*** be examined with the invention elected ...". No options are provided. It therefore further follows that since the product-by-process claims ***must*** be examined, it is only reasonable and logical at the same time also to examine the composition claims (Group II), which embrace like subject matter, and which advances the goal of "compact prosecution."

Moreover, as MPEP § 803 notes, if a search and examination of all claims in a restrictable case can be made without serious burden, the Examiner is encouraged to examine all claims on the merits, ***even when*** the application includes claims to independent or distinct

inventions which, obviously, is not the case here. As stated in *Ex parte Kugler*, 88 USPQ 503, 504 (Bd. App. 1950):

> A separate classification of subject matter to be divided is persuasive but not conclusive of independent status and divisibility. The real inquiry should be addressed to the question of whether or not the two forms of claim relate to such separate subject matter that separate patents could be allowed (in the absence of anticipating prior art) without danger of double patenting. It is also believed to be proper to consider the question of whether or not additional work is involved in examining two classes of claims.

Here, it is submitted that the terms of the product claims lead to the conclusion that search and consideration of those claims will embrace the work necessary for search concerning the product-by-process claims, composition claims, and the process claims. See for example, *In re Spada*, 15 USPQ2d 1655 (Fed. Cir. 1990). Thus, these considerations, too, present further reason for why all of claims should be examined in this application.

Additionally, 37 CFR 1.141 and MPEP § 806.05 (i) make clear that "use" claim 14 and composition claims 9-13, likewise, must be examined in this application. As there set forth, if distinctness is not present, as shown above, the "use" claims must be examined even if it could be found that they are distinct from the other groups. Moreover, it further follows that a finding that the products/compositions are patentable necessarily results in a finding that the "use" of the products/compositions are patentable and thus, in this case, again, the goal and interests of "compact prosecution" are served.

Thus, for all of the foregoing reasons, all claims presented above should be examined on the merits in this application.

Claim 8 was rejected under 35 USC § 112, second paragraph. (Paper No. 2, at 5). In making the rejection, the Examiner asserted only that "[i]t is unclear what is claimed, [claim 8] is confusing." (*Id.*)

Initially, in response, we note that the Examiner has not identified what about claim 8 he found "confusing," as was required to make a rejection under 35 USC § 112, second paragraph. See *Ex parte Balzarini*, 21 USPQ2d 1892, 1898 (BPAI 1991). To reject a claim under §112, second paragraph, it is incumbent on the examiner to establish that one of ordinary skill in this art, when reading the claims in light of the supporting specification, "would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims." *Ex parte Wu*, 10 USPQ2d 2031, 2033 (BPAI 1989). This, the Examiner has not done. Merely asserting that a claim "is confusing" does not satisfy the Examiner's burden. For this reason alone, the rejection was improper.

However, to advance prosecution, claim 8 has been amended above to improve readability and, it is submitted, claim 8 complies with the requirements under § 112, second paragraph.

Hence, reconsideration and withdrawal of the §112, second paragraph, rejection, respectfully is solicited.

Claims 1-7 were rejected under 35 USC § 102(b) as anticipated by (1) WO 92/19640, (2) Meittinen, *et al.*, US Patent No. 5,502,045 ("Meittinen"), and (3) Eugster, *et al.*, Abstract No. 120:245603 ("Eugster"). (Paper No. 2 at 6).

In view of the cancellation of claim 7, the rejection of that claim is moot. For the reasons presented below, particularly in view of the amendment to claim 1, reconsideration and withdrawal of the §102 rejection, respectfully are solicited.

In making the rejection, the Examiner summarily contended that "claims 1-7 are rejected . . . as being anticipated by" the three references noted above. (Paper No. 2, at 6).

As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply,* 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). ***Each and every element*** recited in a claim must be found in a single prior art reference and ***arranged as in the claim***. *In re Marshall,* 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.,* 221 USPQ 481, 485 (Fed. Cir 1984). There must be ***no difference*** between what is claimed and what is disclosed in the applied reference. *In re Kalm,* 154 USPQ 10, 12 (CCPA 1967); *Scripps v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). "Moreover, it is incumbent upon the Examiner to ***identify wherein each and every facet*** of the claimed invention is disclosed in the applied reference." *Ex parte Levy*, 17 USPQ2d 1461, 1462 (BPAI 1990).

Here, the Examiner has not identified ***where,*** in any of the references, each and every element is shown and arranged as required by each claim rejected. That, however, was the Examiner's burden.

Meittinen is the US counterpart of WO 92/19640. These references describe β-phytostanol fatty acid esters and ester mixtures and their use for lowering cholesterol levels in serum. However, both references disclose fatty acids contained in vegetable oils. (See, Meittinen, col. 3, line 43 to col. 4, line 19; and Examples 1-5, col. 5, line 32 to col. 6, line 57). Meittinen fails to disclose eicosapentaenoic acid or docosahexaenoic acid, as required by claim 1 and, hence, all claims dependent therefrom. Therefore, Meittinen does not anticipate claims 1-6.

Eugster discloses esters of saturated and unsaturated dicarbonic acids with sterols. As noted above, claim 1 recites the monocarbonic acids eicosapentaenoic acid and docosahexaenoic acid. Eugster fails to disclose the monocarbonic acids as required by claim 1 and, hence, all claims dependent therefrom. Therefore, Eugster does not anticipate claims 1-6.

Thus, each of the §102 rejections should be withdrawn.

In view of the foregoing, favorable action on the merits including entry of the amendments, reconsiderations and withdrawal of each of the rejections, and allowance of all the claims, respectfully, is solicited.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231, on July 14, 2000.

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Respectfully submitted,

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